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| 4743 | 7590 | 06/04/2007 | EXAMINER | |
| MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606 | | | FLOOD, MICHELE C | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/664,468 | BAGCHI, DEBASIS | |
| | Examiner | Art Unit | |
| | Michele Flood | 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 February 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 51-83 is/are pending in the application.
- 4a) Of the above claim(s) 54-70 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 51-53 and 71-83 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on February 20, 2007 with the cancellation of Claims 1-38 and the addition of newly added Claims 71-83.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Newly amended/submitted claims 54-57 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the subject matter of newly amended Claims 54-57 are directed to a method of administering two or more berry extracts selected from a claim-designated Markush group wherein the composition is administered in a range or approximately 18 to 270 milligrams per dose, whereas the invention originally claimed was directed to a composition comprising two or more berry extracts wherein the composition has a higher antioxidant capacity than any one berry extract used in the composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 54-57 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 51-53 and 71-83 are under examination

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 51-53 and 71-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly rejected as necessitated by amendment.

Claim 51, 71, 72, 76, 75, 76, 79, 80 and 83 are rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art). For example, is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? In addition, from what part(s) of the plant is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on

Art Unit: 1655

the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the desired functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the step(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

Applicant argues that the meaning of the term “berry extract” is well known by one of ordinary skill in the art to mean an aqueous extract of a berry. Applicant’s argument has been fully considered. However, it is unclear as to how Applicant has arrived to this conclusion without supporting documentation teaching or suggesting Applicant’s definition of the term “berry extract”. Thus, for the reason set forth in the previous Office action with regard to the term “extract”, the rejection remains the same.

Claims 53, 74 and 82 are rendered vague and indefinite by the phrase, “wherein the composition has an oxygen radical absorbance capacity above 40 Troxol equivalents/gram fresh weight basis”, because the claims fail to recite a unit of capacity for the measurement of “Troxol (obvious misspellings of the term ‘Trolox’) equivalents”. For example, as discussed at <http://www.nutraceuticalsworld/March042.htm> (, U) “Trolox, a water-soluble vitamin E analog, is used as the calibration standard and the

ORAC [Oxygen Radical Absorbance Capacity] result is expressed as micromole Trolox equivalent (TE) per gram." See page 3. Given the foregoing, the lack of clarity renders the claims very ambiguous.

The metes and bounds of Claims 71, 75, 79 and 83 are rendered vague and indefinite by the recitation of the claims in their entirety because it is unclear as to what is the subject matter to which Applicant seeks patent protection. For instance, the subject matter of independent Claims 51, 72, 76 and 80 from which Claims 71, 75, 79 and 80 depend, respectively, is drawn to a composition comprising two or more berry extracts selected from a claim-designated Markush group. However, Claims 71, 75, 79 and 83, merely recite that the instantly claimed compositions by weight is approximately claim-designated percentage amounts of each of the berry extracts recited in the claim-designated Markush group. As presently drafted, it is unclear as to whether the claim-designated percentage amounts refer to the amounts of the individual two or more berry extracts that may comprise the claimed compositions or whether the claimed compositions comprise each and every of the berry extracts in the claim-designated percentage amounts. The lack of clarity is further exacerbated because the claim-designated percentage amounts are not set forth in terms of the total weight of the composition. See following rejection set forth immediately below.

The metes and bounds of Claims 71, 75, 79 and 83 are rendered uncertain because the percentage amounts of the ingredients are not set forth in terms of either "by weight" or "by volume" percentage amount of the total amount of the composition.

Art Unit: 1655

The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claims 51, 71, 72, 75, 76, 79, 80 and 83 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethnopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical noted in this application. This rejection is made with particular to the recitation of the terms "wild blueberry" and "wild bilberry", which appear in Claims 76, 79, 80 and 83.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claims 53, 74, 78 and 82 are objected to for the following informality: There is an obvious typographical error in the claims. Applicant may overcome the objection by replacing "Troxol" with Trolox.

Claims 71, 75, 79 and 83 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claim in independent form. In the instant

case, the claims fail to further limit the subject matter of independent Claims 51, 72, 76 and 80.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 51-53 and 71-83 are rejected under 35 U.S.C. 102(a) as being anticipated by Cape Cod Biolabs (V). Newly applied as necessitated by amendment.

Applicant claims a composition comprising two or more berry extracts selected from the group consisting of blueberry extract, bilberry extract, cranberry extract, elderberry extract, raspberry extract and strawberry extract, wherein the composition has a higher antioxidant capacity than any one berry extract used in the composition. Applicant further claims the composition of claim 51, wherein the composition has a higher oxygen radical absorbance capacity than the oxygen radical absorbance capacity of any one berry extract used in the composition; wherein the composition has an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis; and, wherein the composition by weight is approximately 50% blueberry extract, 35% strawberry extract, 7.5% cranberry extract, 2.5% raspberry extract, 2.5% elderberry extract and 2.5% bilberry. Applicant claims a composition comprising two or more berry extracts selected from the group consisting of blueberry extract, bilberry extract, raspberry extract and strawberry extract, wherein the composition has a higher antioxidant capacity than any one berry extract used in the composition. Applicant further claims the composition of claim 72, wherein the composition has a higher oxygen radical absorbance capacity than the oxygen radical absorbance capacity of any one berry extract used in the composition; wherein the composition has an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis; and, wherein the composition by weight is approximately 50% blueberry extract, 25% strawberry extract, 12.5% bilberry extract and 12.5% raspberry extract. Applicant claims a composition

comprising two or more berry extracts selected from the group consisting of wild blueberry extract, wild bilberry extract, cranberry extract, elderberry extract, raspberry extract and strawberry extract, wherein the composition has a higher antioxidant capacity than any one berry extract used in the composition. Applicant further claims the composition of claim 76, wherein the composition has a higher oxygen radical absorbance capacity than the oxygen radical absorbance capacity of any one berry extract used in the composition; wherein the composition has an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis; and, wherein the composition by weight is approximately 50% wild blueberry extract, 35% strawberry extract, 7.5% cranberry extract, 2.5% raspberry seed extract, 2.5% elderberry extract and 2.5% wild bilberry extract. Applicant claims a composition comprising two or more berry extracts selected from the group consisting of wild blueberry extract, wild bilberry extract, raspberry seed extract and strawberry extract, wherein the composition has a higher antioxidant capacity than any one berry extract used in the composition.

Applicant further claims the composition of claim 80, wherein the composition has a higher oxygen radical absorbance capacity than the oxygen radical absorbance capacity of any one berry extract used in the composition; wherein the composition has an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis; and, wherein the composition by weight is approximately 50% blueberry extract, 25% strawberry extract, 12.5% wild bilberry extract and 12.5% raspberry seed extract.

Cape Cod Biolabs (CCB) teaches a composition with the trademark name, EYE-MAX®, which comprises a combination of BLUE-MAX® (read herein as a wild blueberry

Art Unit: 1655

extract, absent evidence to the contrary) and BIL-MAX® (read herein as a wild bilberry extract, absent evidence to the contrary) with Lutein.

CCB does not expressly teach that the reference composition has an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis. However, the composition taught by CCB comprises one and the same ingredients disclosed by Applicant as having the claim-designated property. Therefore, an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis is considered inherent to the composition taught by CCB, absent clear and convincing evidence to the contrary.

The reference anticipates the claimed subject matter.

Claims 51-53 and 71-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Powrie et.al. (A*), as evidenced by the teachings of Shanbrom (B), Ou et al. (C*), Wang et al. (W) and Mann (D*).

Applicant's claimed invention was set forth above. Newly applied as necessitated by amendment.

At [0160], Powrie teaches a composition comprising concentrated cranberry juice (read herein as a cranberry extract); concentrated blue juice (read herein as either a blue berry or wild berry extract); and black raspberry juice (read herein as a raspberry seed extract, since Powrie does not teach separating the seeds from the fruit).

Powrie does not expressly teach that the reference composition has

Art Unit: 1655

an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis.

However, the composition taught by Powrie comprises one and the same ingredients disclosed by Applicant as having the claim-designated property. Therefore, an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis is considered inherent to the composition taught by Powrie, absent clear and convincing evidence to the contrary.

Moreover, as evidenced by the teachings of Shanbrom at [0025], cranberry, blueberry and raspberry juices have high antioxidant capacity. For example, Ou teaches that the ORAC value of blueberry juice is 3.16 and that the ORAC value of raspberry juice is 2.34, wherein the ORAC values are expressed as micromole Trolox equivalent per liter ($n>3$). See Table 2. According to Wang, for fresh black raspberry fruits ORAC values range from $16.1 +/ - 0.6$ to $33.7 +/ - 4.0$. See Table 2. Finally, Mann teaches that cranberry juice has a ORAC value of 0.007.

The reference anticipates the claimed subject matter.

Claims 51-53, 71 and 76-79 are rejected under 35 U.S.C. 102(b or e) as being anticipated by Nair et al. (N or E*), as evidenced by the teachings of Prior et al. (X). Newly applied as necessitated by amendment.

Applicant's claimed invention was set forth above.

Nair teaches a composition comprising artemis bilberry extract (read herein as wild bilberry extract) and elderberry extract in Table 11 (see Column 44).

Nair does not expressly teach that the reference composition has

an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis. However, the composition taught by Nair comprises one and the same ingredients disclosed by Applicant as having the claim-designated property. Therefore, an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis is considered inherent to the composition taught by Nair, absent clear and convincing evidence to the contrary.

Moreover, as evidenced by Prior, bilberry extracts have an ORAC value of 44.6 +/- 2.3 expressed as micromole Trolox equivalents per gram of fresh fruit. See Table 2 on page 2689.

The reference anticipates the claimed subject matter.

Claims 51-53 and 71-83 are rejected under 35 U.S.C. 102(e) as being anticipated by Heeg et al. (F*).

Applicant's claimed invention was set forth above.

Heeg teaches a composition comprising cranberry seed oil extract and one or more other berry seed oil extract, including strawberry oil, raspberry oil and blueberry oil. See patent claims 13 and 14. The cranberry seed oil extract taught by Heeg is extracted from cranberry seeds that comprise a portion of the cranberry pulp; and, has a high concentration of tocopherols (alpha- and gamma-tocopherols). See [0032] and [0024], respectively.

Heeg does not expressly teach that the reference composition has

an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis. However, the composition taught by Heeg comprises one and the same ingredients disclosed by Applicant as having the claim-designated property. Therefore, an oxygen radical capacity above 40 Trolox equivalents/gram fresh weigh basis is considered inherent to the composition taught by Heeg, absent clear and convincing evidence to the contrary.

The reference anticipates the claimed subject matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
May 14, 2007